

# **EXHIBIT 19**

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL	:	MDL No. 2804
PRESCRIPTION OPIATE	:	CASE NO. 17-MD-2804
LITIGATION	:	(DAP)
	:	

EXPERT REPORT OF CRAIG J. MCCANN, PH.D., CFA  
March 25, 2019

can also refer to the amount by which a quantity of one in the transaction falls short of or exceeds the standard size package of the NDC.<sup>19</sup>

*16. Transaction Date*

47. Transaction Date is the date a shipment occurred, not the date an order was placed by the Buyer or received by the Seller or the date of some other activity.<sup>20</sup>

*17. Calculated Base Weight in Grams*

48. The Calculated Base Weight in Grams is the total active ingredient weight, in grams, of a drug in the reported transaction. The Calculated Base Weight in Grams in the ARCOS Data produced by the DEA was not reported by the Sellers. Rather, it was calculated by the DEA and appended (along with information about the Buyer and the Seller, the Drug Code, the Drug Name, and the Dosage Units) by the DEA before the data was produced. As explained in Appendix 2, I verify the Calculated Base Weight in Grams for each transaction using the NDC Dictionary.

*18. Dosage Units*

49. Dosage Units is the number of packages in the transaction, multiplied by the number of discrete individual drug products (e.g., pills, patches, lozenges) in each package. Dosage Unit is only populated if the drug product is delivered as a capsule, tablet, film, suppository, patch, lollipop, or lozenge. The Dosage Unit in the ARCOS Data was not reported by the Sellers. Rather, it was calculated by the DEA and appended by the DEA before the

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<sup>19</sup> ARCOS Handbook, §5.17, p. 5-43.

<sup>20</sup> ARCOS Handbook, §5.15.1, p. 5-40.

### B. Defendants' Transaction Data


72. In addition to receiving the ARCOS Data produced by the DEA, I received transaction data produced in discovery by 13 Defendants.<sup>29</sup> I

<sup>29</sup> The 13 Defendants are Anda, AmerisourceBergen, Cardinal Health, CVS, Discount Drug Mart, HBC, Henry Schein, H. D. Smith, McKesson, Prescription Supply, Rite Aid, Walgreens, and Walmart. I do not discuss the data produced by Rite Aid or Henry Schein because the produced data was insufficient to compare with the ARCOS Data. Rite Aid did not produce the Buyer's DEA numbers, and the data produced by Rite Aid does not identify which counties are included in the data. Henry Schein did not include the Buyer's DEA numbers or NDCs. Appendix 7 lists the data fields provided by each Defendant. I have standardized the names of the fields to simplify the presentation.

73. Table 13 presents summary statistics comparing the ARCOS Data and the Defendants' transaction data, sorted by the degree of overlap between the ARCOS Data and the Defendants' transaction data. The transactions summarized in Table 13 consist of all transactions by the Defendants with retail Buyers in Cuyahoga and Summit Counties from January 1, 2006 through December 31, 2014, involving the [REDACTED] opioids in Table 1.<sup>31</sup>

74. At first glance it appears that there is significant non-overlap between the data the Defendants produced to ARCOS in real time, which the DEA then produced, and the data the Defendants produced in discovery but after making some minor adjustments the non-overlap is quite small.

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75. Using my initial matching criteria, [REDACTED] of all MME in either the ARCOS Data or the datasets produced by Defendants are in both the ARCOS Data and the datasets produced by Defendants (i.e., the MME are in the intersection of the ARCOS Data and the datasets produced by Defendants).

76. The amount of MME found in both the ARCOS Data and the datasets produced by Defendants increases if I relax the stringent matching rules I imposed. As discussed more fully below, allowing matches to cross to an adjacent month increases the MME found in both the ARCOS Data and the datasets produced by Defendants by [REDACTED] MME. Correcting Buyer information (e.g., DEA numbers and county) increases the MME in both the ARCOS Data and the datasets produced by Defendants by an additional [REDACTED] MME.

77. The remainder of this section of the report includes a more detailed explanation of the MME that is either (1) in the ARCOS data but not in the datasets produced by Defendants, or (2) in the datasets produced by Defendants but not in the ARCOS Data for each Defendant listed in Table 13.

## **IX. Transaction Analysis**

130. I implemented various approaches to identify transactions meeting specified criteria using the non-public ARCOS Data from 2006 to 2014, supplemented with Defendant transaction data where the ARCOS Data is obviously missing transactions that are included in the transactions produced by Defendants in discovery and to the extent I have Defendant transaction data for the periods before 2006 and after 2014. I calculated the results separately for each of twelve controlled substance drug codes.<sup>54</sup>

### **A. Maximum Monthly, Trailing Six-month Threshold**


131. Under the first approach, I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months. For example, if the number of dosage units containing hydrocodone shipped from a Distributor to a Pharmacy in February, March, April, May, June, and July were 5,000; 10,000; 7,000; 8,000; 9,000; and 9,500 respectively, a requested transaction in August would be flagged if it would cause the number of dosage units containing hydrocodone the Distributor shipped to the Pharmacy to exceed 10,000. Any reported transactions containing hydrocodone on that date and all reported transactions containing hydrocodone from that Distributor to that Pharmacy thereafter are flagged.



132. In this approach and the others implemented below I have been asked by Counsel to assume that the Distributor did not effectively investigate


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<sup>54</sup> I do not analyze transactions in two treatment drugs: buprenorphine and methadone.

the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.

133. Figure 11 illustrates total opioid transactions from Distributors to retail and chain pharmacies into Cuyahoga County from 1996 to 2018. The Trailing Six-Month Maximum Threshold methodology flags 

  
 Additional charts and tables reflecting the result of applying this methodology and the methodologies below to each Distributor are in Appendix 10.

134. Figure 12 illustrates total transactions from Distributors to retail and chain pharmacies into Summit County from 1996 to 2018. The Trailing Six-Month Maximum Threshold methodology flags  of transactions



accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Summit County.



135. Table 24 and Table 25 summarize the transactions in transactions flagged based on the Trailing Six-Month Maximum Threshold Approach in Cuyahoga and Summit Counties.



**B. Twice Trailing Twelve-Month Average Pharmacy Dosage Units**


136. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor. I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.

137. Figure 13 illustrates total opioid shipments into Cuyahoga County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after 2014. The Twice Trailing Twelve-Month Average Pharmacy Dosage Units Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Cuyahoga County.



138. Figure 14 illustrates total shipments into Summit County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after 2014. The Twice Trailing Twelve-Month Average Pharmacy Dosage Units Threshold

methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped to Summit County.



139. Table 26 and Table 27 summarize the transactions in transactions flagged based on the Twice Trailing Twelve-Month Average Pharmacy Dosage Units Threshold in Cuyahoga and Summit Counties.



**C. Three Times Trailing Twelve-Month Average Pharmacy Dosage Units**

140. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor. I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.

141. Figure 15 illustrates total opioid shipments into Cuyahoga County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after 2014. The Three Times Trailing Twelve-Month Average Pharmacy Dosage Units Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Cuyahoga County.



142. Figure 16 illustrates total shipments into Summit County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after 2014. The Three Times Trailing Twelve-Month Average Pharmacy Dosage Units Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of



dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Summit County.



143. Table 28 and Table 29 summarize the transactions in transactions flagged based on the Three Times Trailing Twelve-Month Average Pharmacy Dosage Units Threshold in Cuyahoga and Summit Counties.





**D. Maximum 8,000 Dosage Units Monthly**

144. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units. I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.

145. Figure 17 illustrates total opioid shipments into Cuyahoga County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after

2014. The Maximum 8,000 Dosage Units Monthly Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Cuyahoga County.



146. Figure 18 illustrates total shipments into Summit County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after 2014. The Maximum 8,000 Dosage Units Monthly Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Summit County.



147. Table 30 and Table 31 summarize the transactions in transactions flagged based on the Maximum 8,000 Dosage Units Monthly Threshold Approach in Cuyahoga and Summit Counties.






### **E. Maximum Daily Dosage Units**

148. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation.<sup>55</sup> I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.

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<sup>55</sup> Maximum Daily Dosage Units used as specified in CAH\_MDLPRIORPRO\_DEA07\_01384160

149. Figure 19 illustrates total opioid shipments into Cuyahoga County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after 2014. The Maximum Daily Dosage Units Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Cuyahoga County.



150. Figure 20 illustrates total opioid transactions into Summit County. The Maximum Daily Dosage Units Threshold methodology flags [REDACTED] of transactions accounting for [REDACTED] of dosage units, [REDACTED] of MME and [REDACTED] of drug weight shipped into Summit County.





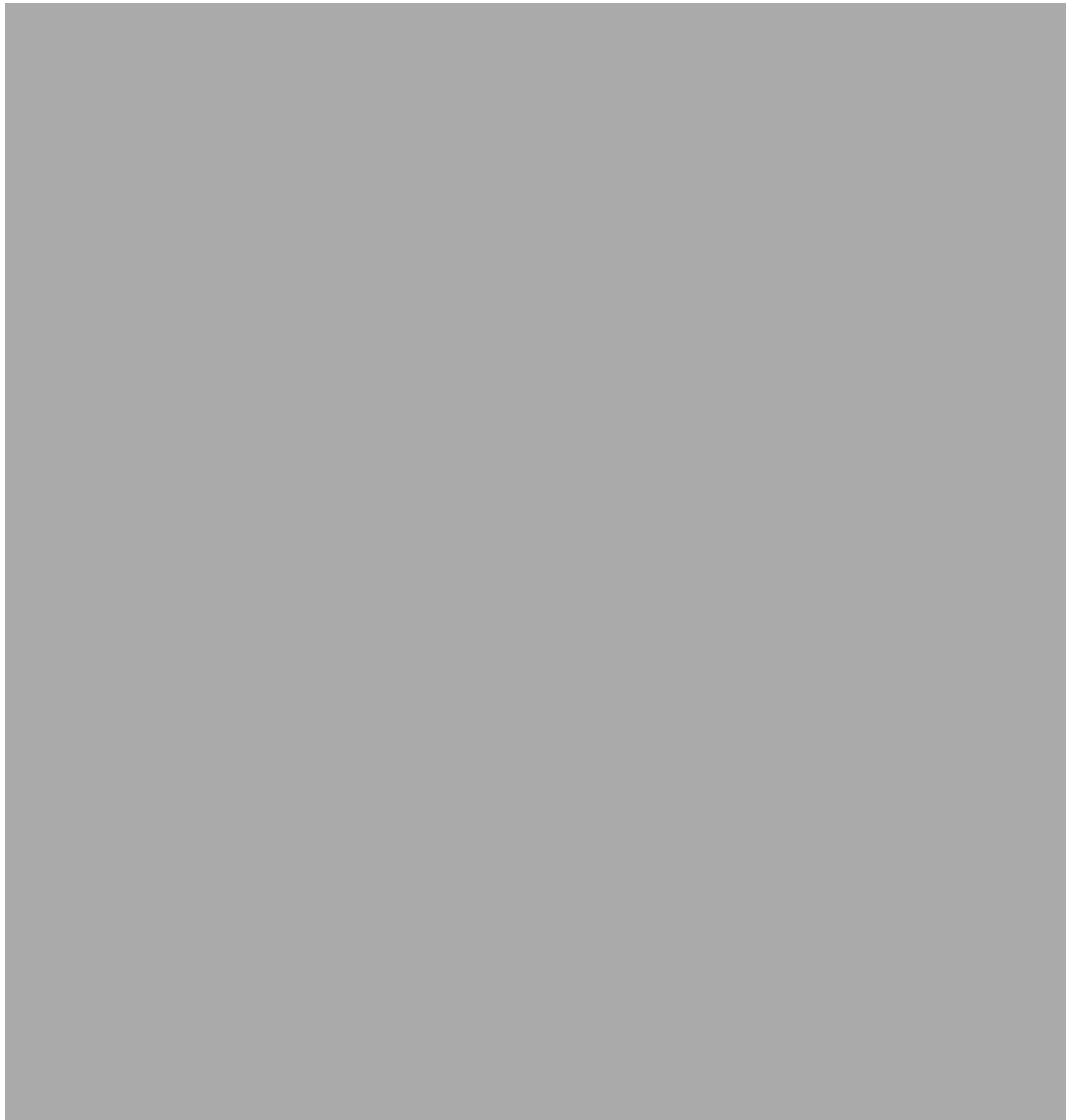
151. Table 32 and Table 33 summarize the transactions in transactions flagged based on the Maximum Daily Dosage Units Threshold Approach in Cuyahoga and Summit Counties.

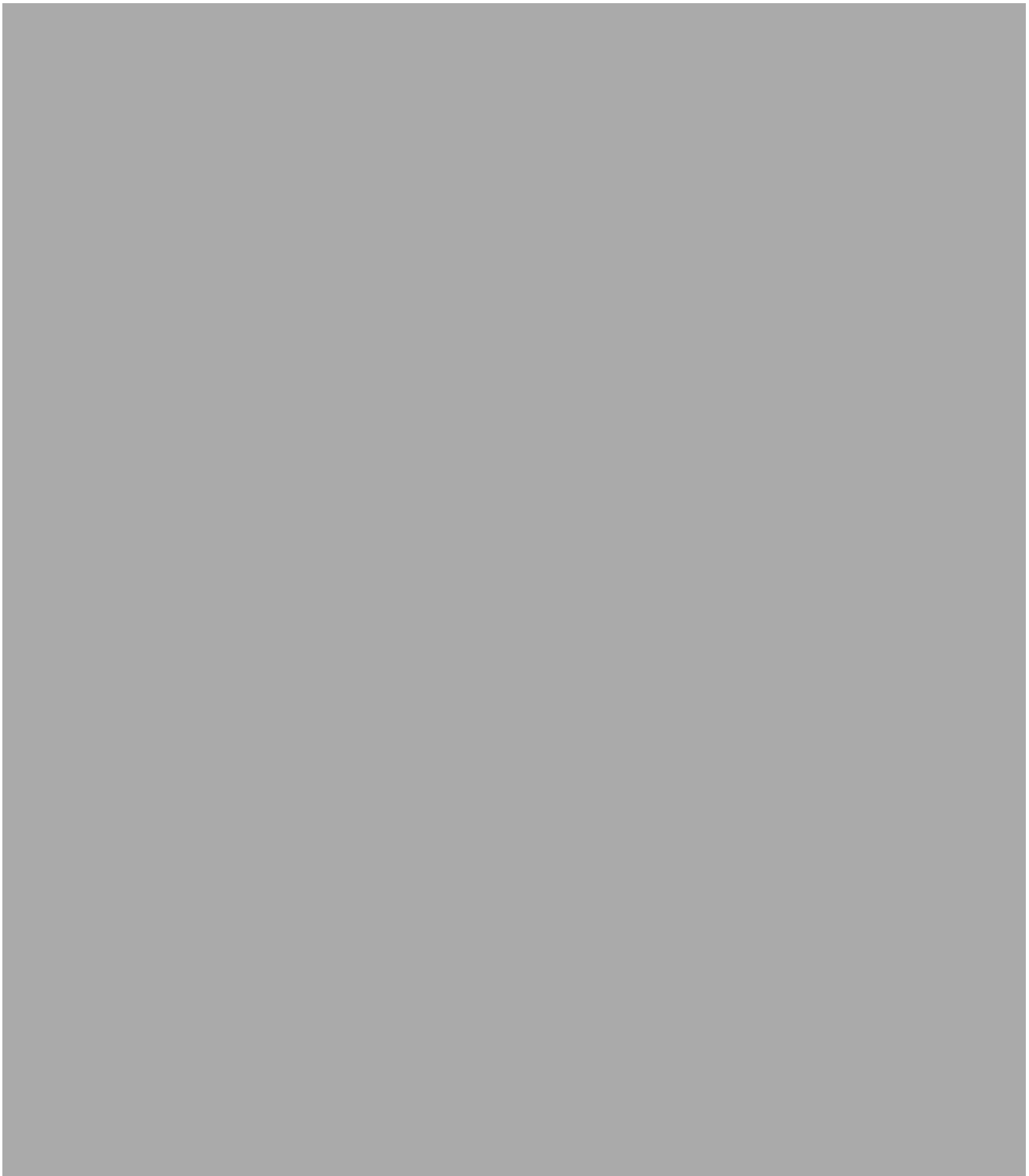


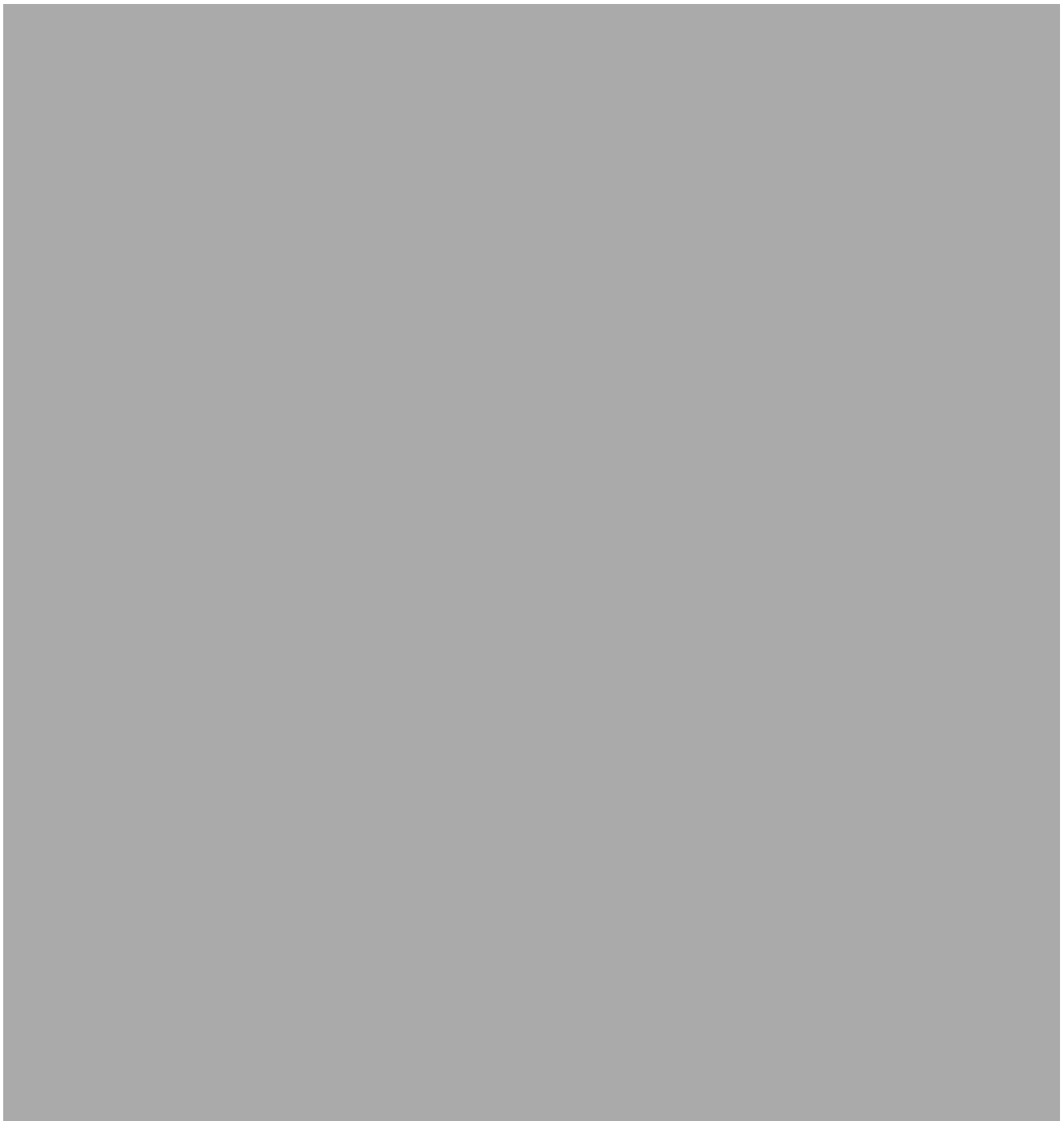


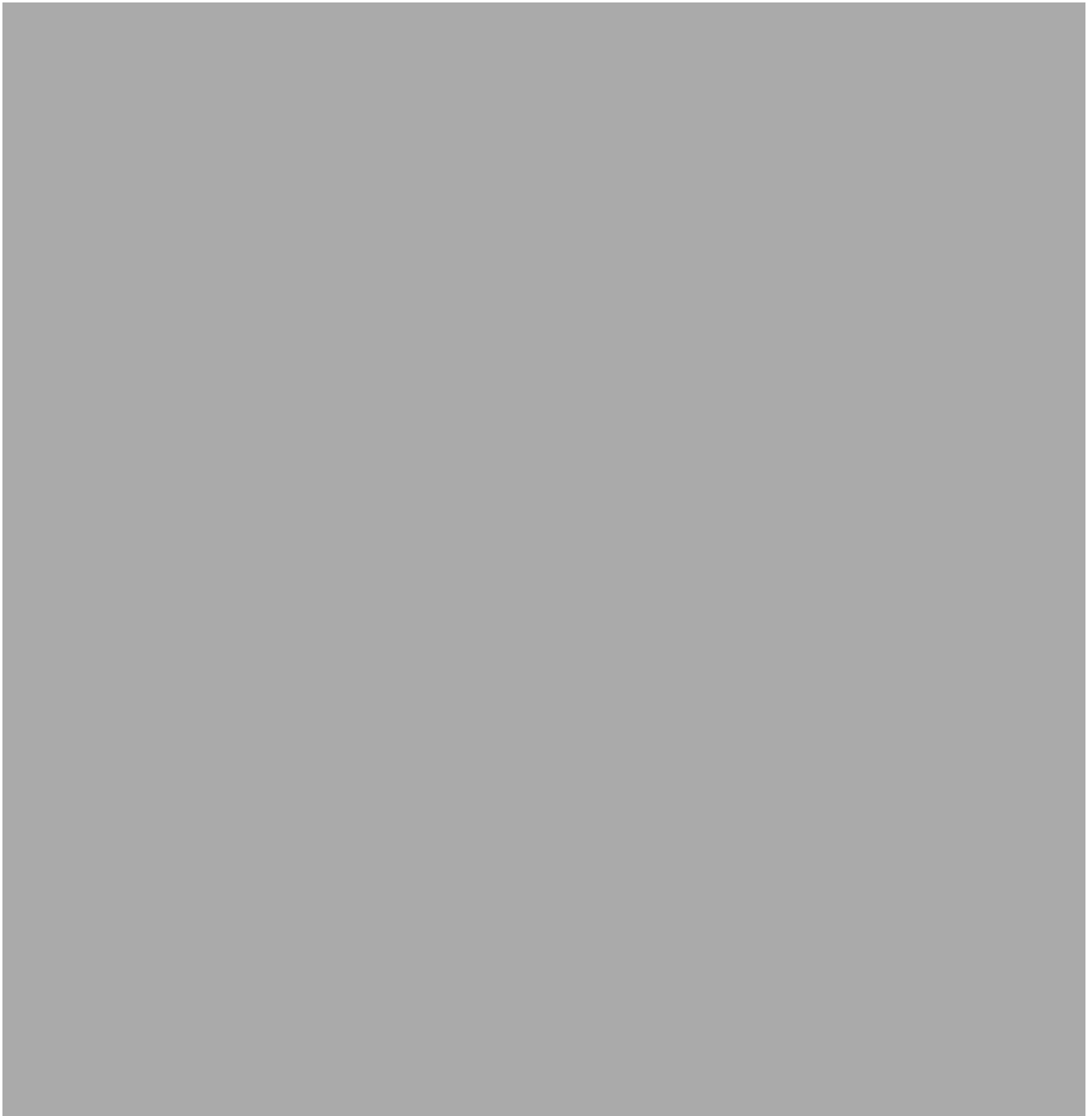
### **F. Additional Identification**

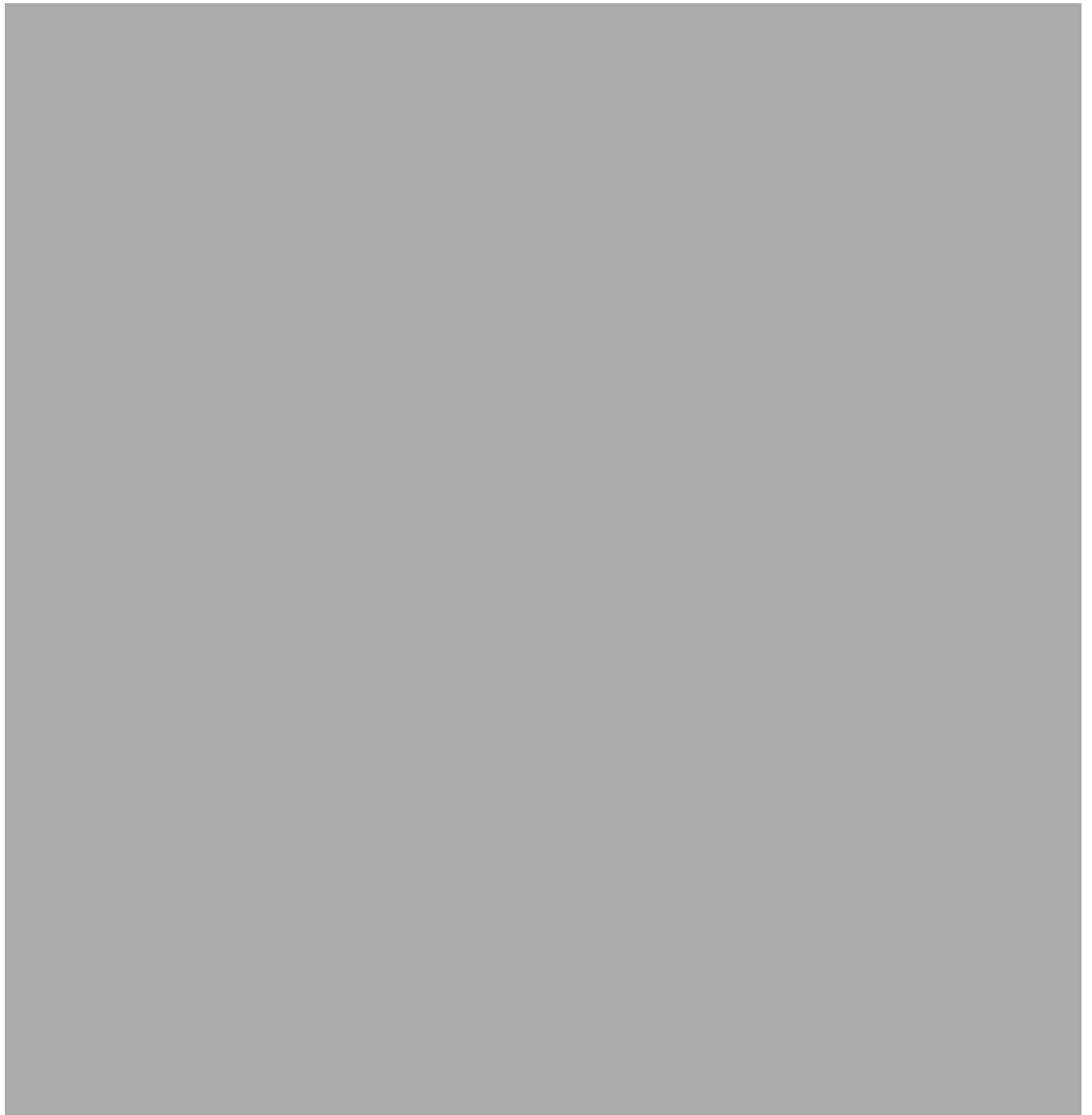
152. I have been asked by Counsel to assume that Chain Distributors may have had knowledge of - or information available to inform them of – opioid shipments from all Distributors to the Chain Distributor’s affiliated pharmacies. I have re-run the five identification routines described above assuming that the Chain Distributors could have flagged transactions based on this expanded information set and report the results for the Chain Distributors in Table 34 through Table 43 below. Additional charts and tables reflecting the result of applying methodologies below to each Chain Distributor are in Appendix 11.













increased from 1997 to 2010 and thereafter declined so that per capita opioid MME in 2017 was [REDACTED] per capita opioid MME in 1997 in Ohio.

155. A possible upper bound on the medically necessary opioid MME per capita baseline is the per capita MME interpolated from 1997 to 2018. This baseline assumes that all prescriptions of opioids in 1997 and in 2018 were medically necessary and that the drivers of legitimate opioid use (eg. aging of the population) evolve gradually rather than discontinuously over time. Plaintiffs allege that opioid consumption in 2018 remained excessive and was still influenced by the Defendants' alleged fraudulent conduct.


156. A possible lower bound on the medically necessary opioid MME per capita baseline is the 1997 per capita MME. This baseline assumes that all prescriptions of opioids in 1997 were necessary and opioid use per capita beyond 1997 levels were unnecessary.

157. I plot these two baselines in Figure 24 along with the per capita MME shipped into Ohio from Figure 21.



158. The difference between the actual shipments of opioids into Ohio and the baseline is an estimate of the excessive opioids shipped into Ohio.

- [REDACTED]  
[REDACTED]  
[REDACTED]
- [REDACTED]  
[REDACTED]  
[REDACTED]



159. Opioid dosage units dispensed in Ohio have declined [REDACTED] from 2012 to 2018. The percentage decline in dosage units dispensed in Ohio has increased each year suggesting that even the 2018 levels exceed the medically necessary level. My estimates of excessive opioid shipments into Ohio can be varied to reflect how much, if any, of the increase from 1997 to 2018 in per

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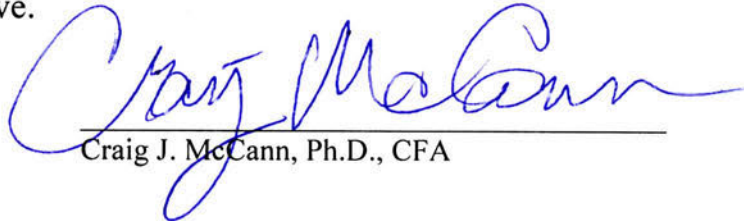
<sup>57</sup> Estimated from the 2017 level reported in the RDSRs and 2018 decline from 2017 reported in Ohio Automated Rx Reports System, 2018 Annual Report, State of Ohio Board of Pharmacy, Section 1, Chart 1 available at [www.ohiopmp.gov/documents/Annual%20Report%20\(2018\).pdf](http://www.ohiopmp.gov/documents/Annual%20Report%20(2018).pdf)

██████ of the opioids dispensed from 1998 to 2017 and ██████ of the opioids dispensed from 2006 to 2014 were excessive.

- If 20% of the increase in opioids dispensed in Ohio in 2018 compared to the 1997 per capita level were medically necessary, ██████ of the opioids dispensed from 1998 to 2017 and ██████ of the opioids dispensed from 2006 to 2014 were excessive.
- If none of the increase in opioids dispensed in Ohio in 2018 compared to the 1997 per capita level were medically necessary, ██████ of the opioids dispensed from 1998 to 2017 and ██████ of the opioids dispensed from 2006 to 2014 were excessive.

160. My estimates of the percentage excessive shipments into Ohio in Table 45 - which average ██████ - are a useful frame of reference for evaluating the transactions flagged by the methods in the previous subsections. For example, the Maximum Monthly Trailing 6-Month Threshold flagged ██████ of transactions, ██████ of dosage units and ██████ of MME shipped to pharmacies in Cuyahoga County and ██████ of transactions, ██████ of dosage units and ██████ of MME shipped to pharmacies in Summit County. The purpose of identifying transactions – to determine which transactions warrant some further due diligence – is likely to only be met by flagging more transactions than those which are used to fill medically unnecessary prescriptions. Thus, the decline in opioid use in Ohio and the implication that more than ██████ of opioids shipped into Ohio were excessive, supports my identification of transactions.

183. The ARCOS Data can be used to identify transactions into a state, county, zipcode or individual pharmacy meeting certain criteria as I have illustrated above.



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